

Exhibit 50



**U.S. Department of Justice
Office of the Inspector General
Evaluation and Inspections Division**

**The Drug Enforcement
Administration's Adjudication
of Registrant Actions**

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EXECUTIVE SUMMARY

INTRODUCTION

The Drug Enforcement Administration (DEA) administers a provision of the *Controlled Substances Act of 1970* requiring registration with the DEA by businesses that import, export, manufacture, or distribute controlled substances; health care practitioners entitled to dispense, administer, or prescribe controlled pharmaceuticals; and pharmacies entitled to fill prescriptions. If the DEA finds a registrant or applicant has violated the Controlled Substances Act, it may issue an order to show cause why registration should not be revoked, suspended, or denied. If the violation poses an imminent threat to public health or safety, the DEA may issue an immediate suspension order, which deprives the registrant of the right to deal in controlled substances immediately.¹ Orders to show cause and immediate suspension orders are collectively known as “registrant actions.”

After receiving notice of a registrant action, the registrant may either allow the DEA Administrator (the Administrator) to issue a final decision or request a hearing through the DEA’s Office of Administrative Law Judges. If the registrant requests a hearing, an Administrative Law Judge (ALJ) will issue a recommended decision to the Administrator. The Administrator then issues a final decision by adopting, modifying, or rejecting the ALJ’s recommended decision. The Office of the Inspector General (OIG) examined the adjudicative process followed by the DEA, the timeliness of that adjudicative process between 2008 and 2012, and the impact of any delays on registrants, the public, and on the DEA itself.

RESULTS IN BRIEF

From 2008 through 2012, we found that the adjudicative process followed by the DEA was in compliance with the requirements of 21 U.S.C. § 824 and the DEA’s regulations.² However, we found that the time it took the DEA to reach a final adjudication of registrant actions was very lengthy. Neither federal law nor the DEA’s regulations establish timeliness standards, and we found that the DEA generally does not have timeliness standards in place. The only exception is for registrant actions involving immediate suspension orders, where the DEA established a 180-day goal for itself. The DEA told us that this timeline

¹ 21 U.S.C. §§ 823 and 824.

² We did not assess the substantive basis for the DEA’s decisions.

was put in place in 2006 chiefly in response to a preliminary injunction issued by a U.S. District Court after finding the DEA violated the due process clause by not providing a timely hearing for a registrant who had received an immediate suspension order. However, we found that from 2008 to 2012 the DEA has consistently failed to meet this timeliness standard.

The DEA is failing to meet its timeliness standards for immediate suspension orders and adjudications take, on average, over a year. The DEA has significantly failed to meet its 180-day timeliness standard for adjudicating immediate suspension orders. The average time for these adjudications ranged from 647 days in 2008 to 459 days in 2012, substantially above the 180-day goal set in a 2006 DEA memorandum.³ Indeed, we found that, from 2008 to 2012, the Office of the Administrator alone took an average of 203 days to issue a final decision after receiving an ALJ's recommended decision. We further found that the Office of the Administrator took, on average, more than 180 days to issue a final decision in 4 of the 5 years we reviewed.

For all registrant actions (involving both orders to show cause and immediate suspension orders), we found that the average number of days the DEA took to make a final decision ranged from a high of 730 days in 2009 to 366 days in 2012. In those cases where the Administrator was the sole adjudicator, the average adjudication time ranged from 303 days in 2008 to 281 days in 2012. While we found that the overall time it takes the DEA to adjudicate registrant actions continues to be very lengthy, the timeliness of the adjudication process nevertheless comports with the applicable laws and regulations, which do not include specific timeliness standards.

Delays in the adjudication process can adversely affect the public, registrants, and the DEA itself. We found that unreasonable delays in the adjudication of registrant actions can have harmful effects on the general public, registrants, and the DEA. Such delays can create risks to public health and safety by allowing noncompliant registrants to operate their business or practice while the registrant action is being adjudicated. For registrants, inappropriate delays can seriously impact their livelihood, career, and ability to conduct business. For the DEA, the failure to timely adjudicate actions against noncompliant registrants

³ The averages were increased by cases in which testimony was provided during proceedings that lasted several years. During administrative proceedings, ALJs have discretion to set deadlines and grant extensions. In one case that lasted over 4 years, the ALJ granted 19 separate requests for an extension by the registrant. We further discuss how ALJs vary in conducting proceedings below.

can impact its mission, slow development of legal precedent, and affect employee morale.

A number of factors may be affecting the timeliness of final decisions. We identified several factors that may be contributing to the length of the DEA's adjudication proceedings. First, the DEA told us that it has devoted more resources to prevent the diversion of prescription drugs for illegitimate purposes, which has led to an increase in the number of registrant actions initiated and a larger adjudicative workload. We also were told by DEA employees that delays resulted from variations between ALJs in how they prefer to manage their caseloads. We further found that timeliness was affected by a lack of guidance about the timeline that DEA attorneys must adhere to when preparing and submitting case summaries and related materials to the Office of the Administrator for adjudications made solely by the Administrator. Finally, we also found that the DEA cannot effectively determine the time it takes to adjudicate each registrant action through final decision.

The DEA has recently taken actions that may improve timeliness. We found that DEA management has recently undertaken efforts to improve timeliness and to facilitate the adjudication of registrant actions. First, from 2008 through 2012, the DEA increased staff in both its Office of Administrative Law Judges and Diversion Litigation Section, which represents the government in registrant actions. Second, the Chief ALJ of the Office of Administrative Law Judges instituted internal policies and training to help ensure the timely processing of registrant actions. Third, the Diversion Litigation Section Chiefs directed attorneys in the section to limit their requests for continuances during the hearing process. Fourth, to improve the hearing process and achieve long-term cost savings, the Office of Administrative Law Judges are now using court rooms equipped with video teleconferencing capabilities. Fifth, the Administrator delegated authority to the Deputy Administrator to review registrant actions and issue final decisions. In addition, the DEA is testing and implementing a new case management system that it hopes will improve case tracking.

RECOMMENDATIONS

In this report, we make three recommendations to improve the DEA's ability to effectively and efficiently adjudicate all registrant actions in a timely manner and mitigate the potential adverse effects of delays on the DEA, registrants, and the public.

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BACKGROUND

Introduction

The Drug Enforcement Administration (DEA) administers a provision of the *Controlled Substances Act of 1970* that requires all businesses that import, export, manufacture, or distribute controlled substances; all health care practitioners entitled to dispense, administer, or prescribe controlled pharmaceuticals; and all pharmacies entitled to fill prescriptions to register with the DEA.⁴ If the DEA finds a registrant has violated the Controlled Substances Act, it may issue an order to show cause why the DEA should not revoke, suspend, or deny a registration. If the violation appears to pose an imminent threat to the public health, the DEA may issue an immediate suspension order, which deprives the registrant of the right to deal in controlled substances immediately.⁵ Orders to show cause and immediate suspension orders are collectively known as “registrant actions.”

The Office of the Inspector General (OIG) examined the DEA’s process for issuing final decisions on registrant actions, the timeliness of the process, and the impact of any delays on registrants, the public, and on the DEA itself.⁶

In this background section, we describe the types of registrants required to register with the DEA, the process by which the DEA adjudicates registrant actions, the number of cases adjudicated by the DEA between 2008 and 2012, and the federal laws and regulations and DEA policy governing the process.

Retail and Wholesale Registrants

As of March 2014, the DEA had 1.5 million active retail and wholesale registrants, as shown in Table 1.

⁴ 21 U.S.C. § 801 et seq. and 21 C.F.R. § 1300 et seq.

⁵ 21 U.S.C. §§ 823 and 824.

⁶ A detailed description of the methodology and analyses for our review is in Appendix I.

Table 1: Retail and Wholesale Registrants, March 2014

Retail Registrants		Wholesale Registrants	
Retail Pharmacy	69,541	Manufacturer	537
Hospital/Clinic	15,992	Distributor	934
Practitioner*	1,172,824	Researcher	9,915
Teaching Institute	311	Analytical Lab	1,509
Mid-Level Practitioner**	243,684	Importer	231
Total Retail Registrants	1,502,352	Exporter	242
		Reverse Distributor	61
		Narcotic Treatment Program	1,360
		Total Wholesale Registrants	14,789
Total Registrants			1,517,141

* Practitioners include physicians, dentists, and veterinarians.

** Mid-level practitioners include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.

Source: DEA Office of Diversion Control.

Retail registrants, such as pharmacies, hospitals, and doctors, must renew their registrations every 3 years. Wholesale registrants, such as manufacturers, distributors, and researchers, must renew every year.

The DEA's Adjudication Process for Registrant Actions

The *Controlled Substances Act of 1970* authorizes the DEA to deny, suspend, or revoke a DEA registration upon a finding that the registrant has materially falsified any registration application filed; been convicted of a felony relating to a controlled substance or a chemical important to the manufacture of a controlled substance; had its state license or registration suspended, revoked, or denied; committed an act which would render the registration inconsistent with the public interest; or been excluded from participation in a Medicaid or Medicare program.⁷ To suspend or revoke a registration, the DEA first serves on the registrant an order to show cause or an immediate suspension order that sets a time and place for a hearing regarding the proposed revocation of a registration. The hearing takes place only if the registrant files a formal request within 30 days of being served with an order to show cause or an immediate suspension order.⁸ A registrant who does not file a request

⁷ 21 U.S.C. § 824(a).

⁸ 21 C.F.R. § 1301.43(a) specifies a 30-day deadline. However, the registrant may request an extension.

for a hearing by the deadline is deemed to have waived the opportunity for a hearing, and the case is forwarded to the Administrator for a final decision.⁹

If the registrant files a request for a hearing, the Office of Administrative Law Judges assigns an ALJ to oversee the matter. The ALJ has the authority to determine in part how quickly cases proceed through the hearing process by setting or extending deadlines.¹⁰ The ALJ issues an order requiring first the DEA and then the registrant to file prehearing statements identifying the issues they intend to litigate in the hearing and the documents and witnesses they plan to introduce.¹¹ The registrant is entitled to hire an attorney to represent it.¹² The DEA is represented by an attorney from the Diversion and Regulatory Litigation Section (Diversion Litigation Section) in the Office of Chief Counsel. Once the statements are filed, the ALJ conducts a prehearing conference to discuss the possibility of settlement and set a hearing date.¹³ Parties may request extensions of deadlines for good cause, and it is within the ALJ's discretion to decide whether to grant those requests. The hearing is held either in person or through video teleconferencing.¹⁴ The ALJ sets a deadline by which both parties may file post-hearing briefs containing proposed findings of fact and conclusions of law.¹⁵

As soon as practicable after the deadline for filing post-hearing briefs, the ALJ issues a recommended decision.¹⁶ Both the registrant and the DEA may file exceptions to the ALJ's opinion if they believe any

⁹ 21 C.F.R. § 1315.56(e).

¹⁰ For example, 21 C.F.R. §§ 1316.54-55, 1316.58, and 1316.64-66 each grant an ALJ some discretion in determining or extending the deadlines for the parties to submit documents.

¹¹ Alternatively, in cases where the registrant's state license to practice medicine has been suspended, revoked, or denied, the DEA may file a motion for summary disposition instead of a prehearing statement. The purpose of a motion for summary disposition is to quickly resolve cases where the registrant no longer meets the criteria to hold a DEA registration.

¹² 5 U.S.C. § 555(b).

¹³ 21 C.F.R. § 1316.54.

¹⁴ Hearings held in person take place either at the Office of Administrative Law Judges in Arlington, Virginia, or at a location convenient to the registrant.

¹⁵ 21 C.F.R. § 1316.64.

¹⁶ 21 C.F.R. § 1316.65(a).

portions of it are erroneous.¹⁷ No sooner than 25 days after the issuance of the recommended decision, the Office of Administrative Law Judges certifies the case record and forwards it to the Office of the Administrator for final review.¹⁸

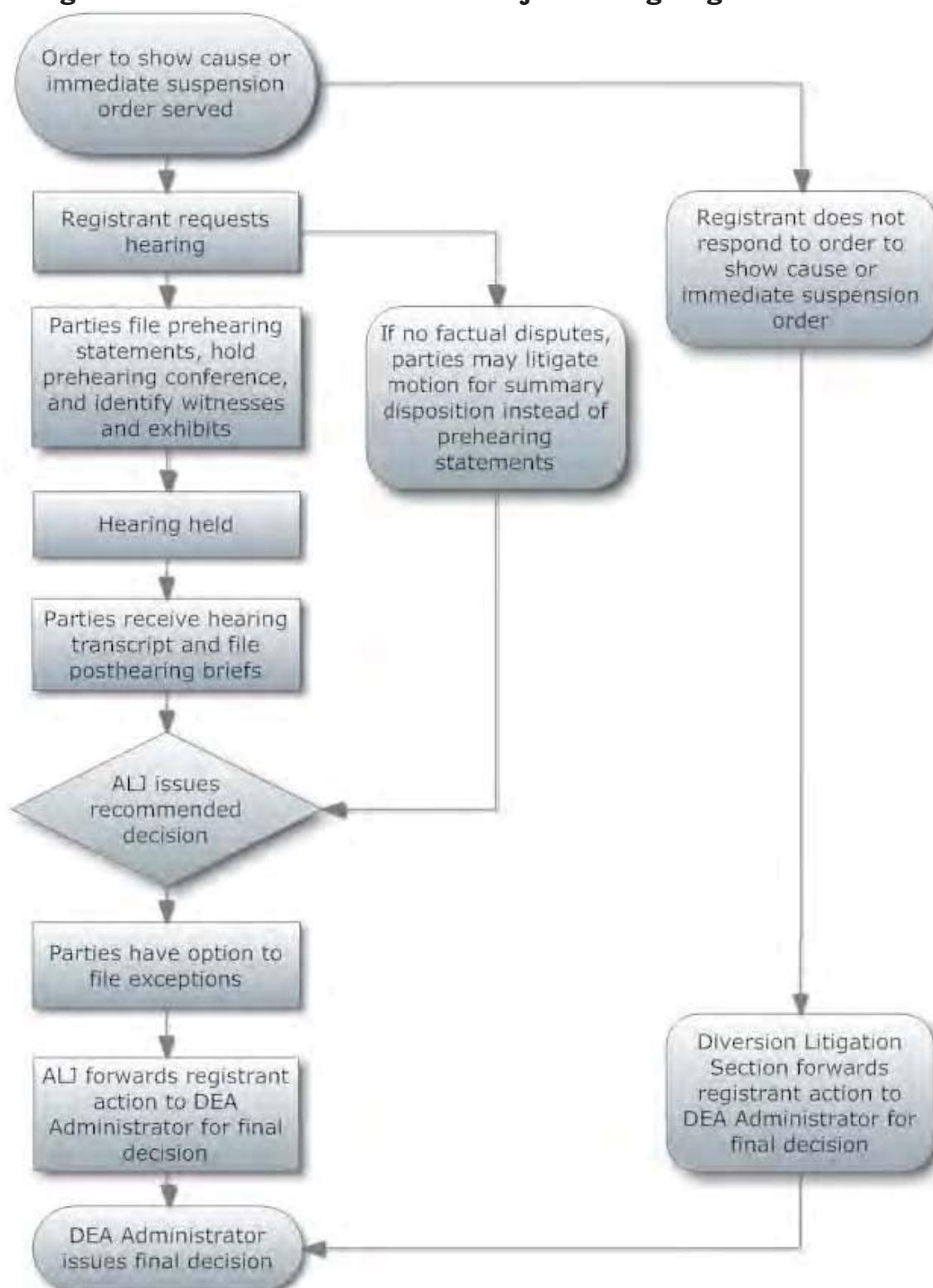
The Administrator issues a final decision by adopting, modifying, or rejecting the ALJ's recommended decision.¹⁹ The Administrator's final decision is published in the *Federal Register*. Registrants have the right to appeal the decision to a U.S. Court of Appeals. If the decision is not appealed, the administrative action is complete. Figure 1 illustrates the process.

¹⁷ 21 C.F.R. § 1316.66. Alternatively, a party may request the ALJ's permission to file a response to the other party's exceptions.

¹⁸ 21 C.F.R. § 1316.65(c).

¹⁹ 21 C.F.R. §§ 1301.46 and 1316.67.

Figure 1: The DEA's Process for Adjudicating Registrant Actions



Sources: Controlled Substances Act regulations and DEA documents.

Number of Cases Adjudicated by the DEA Between 2008 and 2012

The DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. The Administrator was the sole adjudicator for the remaining 61 registrant actions.

According to DEA data, not all registrant actions initiated result in final decisions. For example, while 505 new registrant actions were initiated from 2008 through 2012, only 178 final decisions were issued during that time period.²⁰ DEA personnel told us that cases that do not result in a final decision are closed in other ways, such as negotiating settlements. When the registrant and the DEA pursue settlement discussions during the adjudicative process, they may file prehearing statements and hold prehearing conferences before coming to a settlement agreement and asking the ALJ to terminate the proceedings. DEA personnel told us that negotiating settlements can contribute to the length of time to adjudicate registrant actions that do result in final decision. Specifically, while settlements mean that the ALJ does not have to devote time to holding a hearing or writing a recommended decision, the ALJ must still hold prehearing conferences and review documents that the parties file before they request termination. These activities take time that is no longer available for the ALJ to devote to registrant actions that are not settling and will require hearings and recommended decisions. Settlement negotiations may also keep attorneys from forwarding to the Administrator other registrant actions in which the registrant does not request a hearing.

Federal Laws and Regulations, and DEA Policy, Related to the Adjudication of Registrant Actions

Below is a summary of federal laws and regulations, as well as a DEA policy, regarding the adjudication of registrant actions.

²⁰ We cannot calculate the exact percentage of registrant actions initiated that ended in a final decision because most of the final decisions issued in 2008 were for registrant actions initiated in 2007 or earlier. Similarly, some of the registrant actions initiated in 2012 were still pending at the end of the year. We present both numbers not to calculate the ratio between them, but to illustrate that a final decision is not the end result for most registrant actions that are begun.

- *Controlled Substances Act of 1970* (Pub. L. No. 91-513, 21 U.S.C. § 801 et seq.) regulates the manufacture, importation, possession, use and distribution of certain substances. Part C of the Act requires businesses and practitioners dealing in controlled substances to register with the DEA and establishes the grounds under which the DEA can deny, revoke, or suspend registrations.
- *Administrative Procedure Act* (Pub. L. No. 79-404, 5 U.S.C. § 551 et seq.) establishes administrative procedures for rule making, adjudications, and hearings in the federal government. Specifically, the Act requires that parties to a hearing must be given notice of the time and place of hearings, gives parties the right to be represented by counsel, enumerates the powers of a neutral ALJ to preside over a hearing and make or recommend a decision in the case, and requires that decisions be based exclusively on the case record.
- *Title 21 of the Code of Federal Regulations* § 1301.31-46 and § 1316.41-68 establishes procedures for the DEA to revoke, deny, or suspend registrations and sets a standard of imminent danger to the public health for suspension orders. The regulations outline the requirements for registrants to request hearings, the rules for ALJs to conduct hearings and issue recommended decisions, and the Administrator's responsibility to issue the final decision. The regulations do not set timeliness standards other than giving the registrant 30 days to request a hearing and giving both parties 20 days to submit exceptions after the ALJ issues a recommended decision; however, they do state that the ALJ and Administrator are to issue the recommended and final decisions "as soon as practicable" after the hearing.
- *Memorandum from DEA Deputy Administrator* ("Immediate Suspension of DEA Registration; Hearing Process," issued in October 2006) establishes timeliness standards as a matter of internal DEA policy for adjudicating immediate suspension orders. The memorandum requires an ALJ to commence a hearing within 60 days of the action being issued and to certify the hearing record to the Deputy Administrator within 150 days of a suspension. The memorandum also establishes a goal of issuing a final decision within 180 days of a suspension, giving the Office of the Administrator no more than 30 days after the record is certified. The timeliness standards are exclusive of any continuances requested by the registrant.

RESULTS OF THE REVIEW

From 2008 through 2012, the process followed by the DEA for adjudicating registrant actions was in compliance with 21 U.S.C. § 824 and its own regulations.²¹ However, these federal laws and regulations do not establish timeliness standards for the adjudication of registrant actions. We found that the DEA generally does not have timeliness standards in place for its adjudication of registrant actions. The only exception is for actions involving immediate suspension orders, for which the DEA established timeliness standards in 2006. We found, however, that from 2008 to 2012 the DEA consistently failed to meet these timeliness standards in adjudicating immediate suspension orders. We further found that the DEA's adjudication process for those actions where it had no timeliness standards was very lengthy, although we noted that the DEA's timeliness improved from 2008 through 2012. Despite these improvements over the last few years, we found areas where the DEA could enhance its performance, including establishing timeliness standards for the adjudication of all registrant actions.

In the following sections we discuss: (1) the overall timeliness of the adjudication of registrant actions; timeliness of orders to show cause, immediate suspension orders, and registrant actions adjudicated solely by the Administrator; and the actions the DEA took during the scope of the review to improve timeliness; (2) the impact of delays in the adjudication of registrant actions on registrants, the public, and the DEA; (3) factors that affect timeliness; and (4) actions taken by the DEA that may improve timeliness in the future.

The DEA does not have timeliness standards for most of its registrant actions and is not meeting its timeliness standards for the one area where it does have them.

The laws and regulations establishing the DEA adjudication process do not include timeliness standards for the entire process, and the DEA does not have timeliness standards that apply to all types of registrant actions. However, a 2006 memorandum from the DEA Deputy Administrator (“Immediate Suspension of DEA Registration; Hearing Process,” issued in October 2006) established timeliness standards as a matter of internal DEA policy for adjudicating immediate suspension orders. However, we found that the adjudication of immediate suspension orders fell short of the timeliness standard established in the 2006 memorandum.

²¹ We did not assess the substantive basis for the DEA's decisions.

No timeliness standards apply to all types of registrant actions.

No law or regulation imposes specific timeliness standards for the DEA's registrant action process. The Administrative Procedure Act requires agencies to conclude matters presented to them "within a reasonable time."²² In addition, the Controlled Substances Act regulations require an ALJ to issue a recommended decision "as soon as practicable" after a hearing has been held and the parties have had the opportunity to submit proposed findings of fact and conclusions of law.²³ Similarly, the Controlled Substances Act regulations require the Administrator to issue a final decision "as soon as practicable" after receiving the certified record.²⁴

DEA policy does not specify comprehensive timeliness standards for all registrant actions. However, in October 2006, the DEA issued a memorandum (2006 memorandum) that established timeliness standards for immediate suspension orders.²⁵ According to the Administrator, this memorandum was issued chiefly in response to a preliminary injunction issued by a U.S. District Court after finding that the DEA violated the due process clause of the Fifth Amendment by not providing a timely hearing for a registrant who had received an immediate suspension order.²⁶ The 2006 memorandum establishes that the DEA should issue a final decision within 180 days from the issuance of an immediate suspension order. It also required ALJs to commence a hearing within 60 days of issuance of an immediate suspension order and to submit the certified record of the hearing to the Administrator for a final decision within 150 days of the issuance of an immediate suspension order.

The 2006 memorandum established timeliness standards only for immediate suspension orders where a registrant requests a hearing. The 2006 memorandum did not specify timeliness standards for immediate suspension orders for cases where the registrant fails to request a hearing; such cases are adjudicated solely by the Administrator. Nor did

²² 5 U.S.C. § 555(b).

²³ 21 C.F.R. § 1316.65.

²⁴ 21 C.F.R. §§ 1301.46 and 1316.67.

²⁵ The memorandum was issued by the then-Deputy Administrator, who has since become the Administrator.

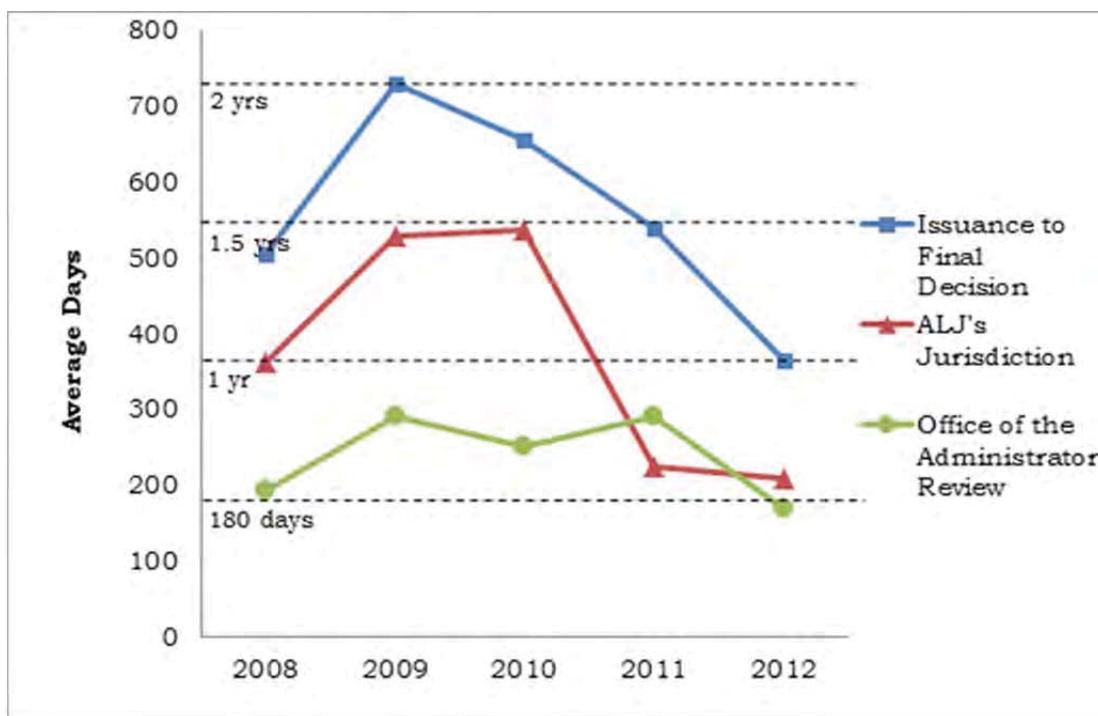
²⁶ See *Apothecary Arts Pharmacy, Inc. v. Gonzales*, No. 06-119 (D.D.C. Feb. 3, 2006) (order granting preliminary injunction and dissolving the DEA's immediate suspension).

the memorandum establish timeliness standards for orders to show cause, either where a registrant requests a hearing or in cases adjudicated solely by the Administrator.

The overall time it takes the DEA to adjudicate registrant actions continues to be very lengthy, although timeliness is improving.

During the period from 2008 through 2012, we found that the average number of days for the DEA to adjudicate registrant actions, from initiation to final decision, peaked in 2009 at 730 days on average (or 2 years) and declined each year thereafter to 366 days on average (or about 1 year) by 2012. Figure 2 shows the DEA's timeliness for adjudicating registrant actions, including the timeliness of the Office of Administrative Law Judges and the Office of the Administrator for all registrant actions from 2008 through 2012.

Figure 2: Average Days to Adjudicate All Registrant Actions by Year, 2008 through 2012



Note: Averages for the time from issuance to final decision include all 178 registrant actions. Averages for the Office of Administrative Law Judges jurisdiction include only the 117 registrant actions that resulted in an ALJ's recommended decision. Averages for the Office of the Administrator include 175 registrant actions, excluding 3 where the DEA could not determine the date of forwarding to the Office of the Administrator.

Source: OIG analysis.

We found that 117 cases during this period came under the Office of the Administrative Law Judges' jurisdiction and that the number of days those cases spent pending with the Office of Administrative Law Judges declined from an average of 362 days in 2008 to an average of 210 days in 2012, an improvement of 152 days or about 5 months.²⁷ The Office of the Administrator was responsible for all 178 registrant actions beginning when they were forwarded by the Office of Administrative Law Judges or the Diversion Litigation Section until a final decision was issued.²⁸ The Office of the Administrator's average time for reviewing cases improved between 2008 and 2012, declining from 194 days on average in 2008 to 169 days on average in 2012, an improvement of about a month.

In the following sections, we separately assess the DEA's timeliness in adjudicating orders to show cause and immediate suspension orders, as well as registrant actions adjudicated solely by the Administrator without an ALJ's recommended decision. We also discuss steps DEA management took to improve the timeliness of the adjudication of registrant actions, as well as how enforcement operations and administrative procedures can affect the timeliness of issuing final decisions.

The DEA consistently failed to meet its own timeliness standards in adjudicating immediate suspension orders.

As stated above, the 2006 memorandum establishes a goal to issue final decisions for immediate suspension orders in 180 days. The memorandum further provides that an ALJ must commence a hearing within 60 days after an immediate suspension order is issued unless the registrant requests a continuance, waives the right to a hearing, or fails to respond. The memorandum additionally requires the Office of Administrative Law Judges to submit a certified record and recommended decision to the Office of the Administrator no more than 150 days after the immediate suspension order is issued, although this deadline can be extended by the length of any continuance requested by a registrant. Thus, under these time frames, the Office of the

²⁷ We excluded 11 registrant actions from this analysis where the registrant requested a hearing but the ALJ terminated the proceedings without issuing a recommended decision. In an additional 50 registrant actions, the registrant did not request a hearing. We discuss these 61 registrant actions below as part of our analysis of cases adjudicated solely by the Administrator.

²⁸ The Diversion Litigation Section forwards actions to the Office of the Administrator when the registrant does not request a hearing or the proceedings are terminated without issuing a recommended decision by an ALJ.

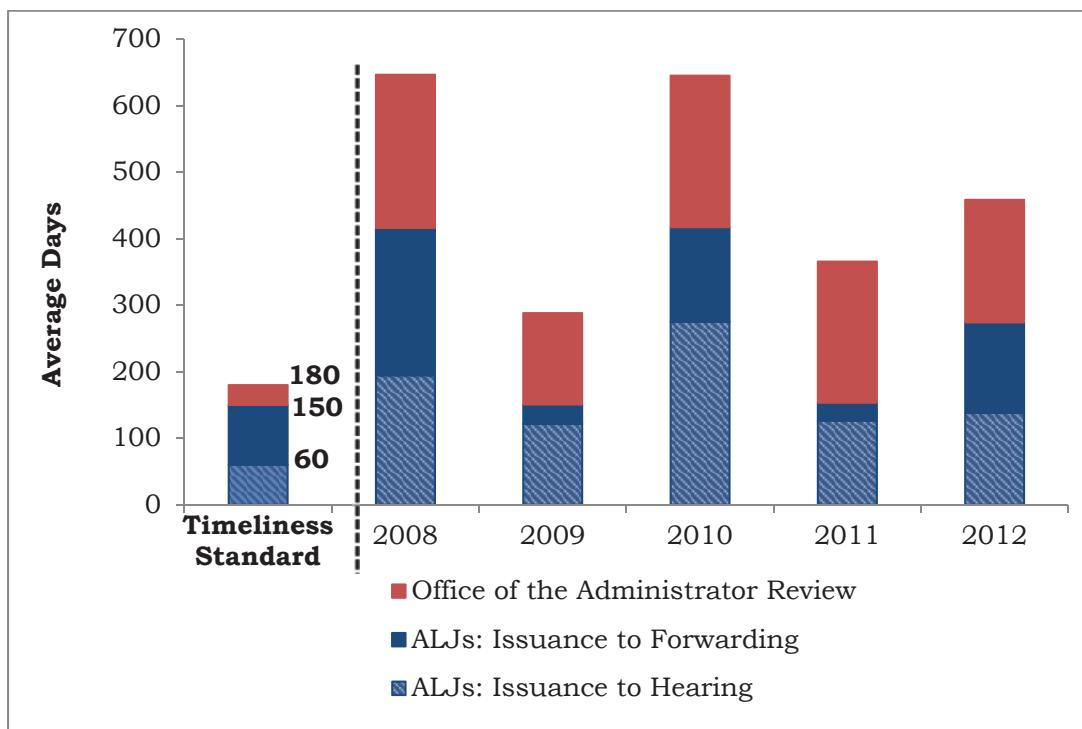
Administrator would have 30 days to issue a final decision after the time allowed for the Office of Administrative Law Judges to submit the certified record.

We found that the DEA's adjudication of these cases was not compliant with the timeliness standards the DEA established in the 2006 memorandum. Specifically, we found that the average number of days to adjudicate immediate suspension orders with an ALJ's recommended decision ranged from 647 days on average in 2008 to 459 days on average in 2012.²⁹ We also found that the average time for the Office of Administrative Law Judges to adjudicate immediate suspension orders, starting when the immediate suspension order was issued and ending when a recommended decision was forwarded to the Office of the Administrator, ranged from 416 days on average in 2008 to 274 days on average in 2012.³⁰ Finally, we found that the Office of the Administrator itself took from 231 days on average in 2008 to 185 days on average in 2012 to issue a final decision. Figure 3 shows the timeliness of the adjudication of immediate suspension orders based on timeliness standards identified in the 2006 memorandum.

²⁹ The averages were increased by cases in which testimony was provided during proceedings that lasted several years. During administrative proceedings, ALJs have discretion to set deadlines and grant extensions. In one case that lasted over 4 years, the ALJ granted 19 separate requests for an extension by the registrant. We further discuss how ALJs vary in conducting proceedings below.

³⁰ For immediate suspension orders, we based our analysis on the date the orders were issued because that is the date the 2006 memorandum used to calculate timeliness. The average times for the portion of the process that begins with a registrant's request for a hearing and ends when the immediate suspension order is forwarded to the Office of the Administrator for review are 393 days in 2008 and 244 days in 2012.

Figure 3: DEA Timeliness Standards Compared with Average Days to Adjudicate Immediate Suspension Orders with ALJ's Recommended Decision, 2008 through 2012



Note: The averages for Office of the Administrator Review and for the Office of Administrative Law Judges from issuance to forwarding include all 41 cases that fell under the jurisdiction of the Office of Administrative Law Judges and resulted in an ALJ's recommended decision. The average for the Office of Administrative Law Judges from issuance to hearing includes only the 28 cases that had a hearing and resulted in a recommended decision.

Source: OIG analysis.

While the overall adjudication of immediate suspension orders was not compliant with timeliness standards established in the 2006 memorandum, we found that absent requests for continuances from the registrant, the Office of Administrative Law Judges generally met the 150-day standard the memorandum established for aspects of the adjudication process that fell within its jurisdiction.³¹ Specifically, in the 13 immediate suspension orders where the registrants did not request any continuances, we found that the Office of Administrative Law Judges

³¹ Registrants requested 1 or more continuances in 68 percent (28 of 41) of immediate suspension orders that included a recommended decision.

averaged 105 days to forward the certified case file on to the Office of the Administrator.³²

We further found that the average number of days the Office of the Administrator took to issue final decisions for immediate suspension orders exceeded 30 days in all but one immediate suspension order where an ALJ issued a recommended decision. Specifically, for all immediate suspension orders between 2008 and 2012, we found that the Office of the Administrator averaged 203 days to issue final decisions after the Office of Administrative Law Judges forwarded a recommended decision. By itself, this 203-day average for just the Office of the Administrator's review exceeded the 180-day timeliness goal that the 2006 memorandum established for the entire adjudicative process. We further found that the Office of the Administrator exceeded 180 days on average for its review of recommended decisions and issuance of final decisions in 4 of the 5 years within the scope of our review.

The excessive delay in the DEA's handling of adjudications was most clearly evidenced by its failure to timely adjudicate certain cases we reviewed where precedent required revocation. According to DEA officials and staff, some immediate suspension orders do not involve issues that necessitate time-consuming review because agency precedent clearly requires revocation. For example, DEA officials and staff told us that DEA precedent requires that a registration be revoked if it is held by a registrant who has lost a state license to practice medicine. In those circumstances where administrative precedent compels revocation, the Office of Administrative Law Judges issues a recommended decision in favor of revocation after the registrant and the Diversion Litigation Section attorney submit arguments on a motion for summary disposition. Between 2008 and 2012, the Administrator made a final decision in 13 cases with immediate suspension orders that involved an ALJ's summary disposition in favor of revocation.³³ In those 13 cases,

³² The 2006 memorandum states that if a registrant requests a continuance, the number of days added to the adjudication of the order as a result do not count toward the Office of Administrative Law Judges' 150-day total. However, while the DEA's case tracking systems can show how many continuances were requested in each registrant action, it cannot show how much time those requests added to the length of the adjudication. We were therefore unable to determine whether the Office of Administrative Law Judges met its 150-day timeframe in cases that included registrant-requested continuances.

³³ Overall, 40 of the 178 registrant actions during the time period of our review involved summary disposition. In addition to the 13 actions discussed above, 27 registrant actions involved summary dispositions following an order to show cause. In these 27 registrant actions, even though the DEA precedent required revocation, the

(Cont'd.)

even though the outcome of revocation was required by DEA precedent, the Office of Administrative Law Judges took an average of 90 days from issuance of the immediate suspension order to forward the ALJ's recommended decision to the Office of the Administrator, and the Office of the Administrator took an average of 203 days to issue a final decision after receiving the case from the Office of Administrative Law Judges.³⁴

The time to adjudicate orders to show cause is very lengthy, although timeliness has recently improved.

As noted previously, the DEA has no timeliness standards for issuing final decisions for actions involving orders to show cause, and we found that the time it took for the DEA to issue final decisions was very lengthy. For example, we found that overall it took the DEA on average 616 days in 2008 to 371 days in 2012 to issue a final decision. We further found that, in 2008, the Office of Administrative Law Judges' jurisdiction averaged 336 days, whereas in 2012 it averaged 181 days. In addition, we found that, in 2008, the Office of the Administrator averaged 244 days to issue a final decision after the Office of Administrative Law Judges forwarded an ALJ's recommended decision, whereas in 2012, the Office of the Administrator averaged 158 days to issue a final decision.

Adjudications by the Office of the Administrator have become less timely for those matters where an ALJ recommended decision was not required.

The regulations establishing the DEA's authority to adjudicate registrant actions do not establish a process for adjudicating cases if the registrant fails to request a hearing, formally waives a hearing, or has hearing proceedings terminated by an ALJ's order.³⁵ Sixty-one (34 percent) of the 178 registrant actions within the time period of our review did not require an ALJ recommended decision for one of these reasons, and therefore were adjudicated solely by the Office of the Administrator. In these circumstances, the DEA has no timeliness standards and the DEA Diversion Litigation Section attorney assigned to

Office of Administrative Law Judges averaged 118 days to issue its summary decision, and the Office of the Administrator averaged 185 days to issue its final decision.

³⁴ We discuss below the DEA's plans to delegate authority to make final decisions in summary disposition cases to the Deputy Administrator.

³⁵ ALJs terminated hearing proceedings in 11 registrant actions for reasons such as the registrant withdrawing a hearing request, the registrant facing prosecution for criminal charges, or the registrant failing to meet deadlines for submitting prehearing documents.

the case is responsible for forwarding the case to the Office of the Administrator for final decision.

We found that the Diversion Litigation Section's time to forward these cases to the Office of the Administrator for a final decision improved from 137 days on average in 2008 to 58 days on average in 2012.³⁶ However, we also found that the Office of the Administrator's time to issue a final decision increased over this same period from an average of 98 days in 2008 to an average of 167 days in 2012. Because the Diversion Litigation Section's improvement was almost entirely offset by an increase in the Office of the Administrator's average time, the time between when the registrant action was issued and when the DEA made its final decision improved only slightly from an average of 303 days in 2008 to 281 days in 2012.³⁷

DEA management took certain steps in an effort to improve the timeliness of the adjudication of registrant actions between 2008 and 2012.

DEA management implemented efforts to improve timeliness during the scope of our review that may have contributed to the improvements in timeliness that we found. For example, the DEA increased the staff in both the Office of Administrative Law Judges and the Diversion Litigation Section from 2008 through 2012 due, in part, to a management decision to use registrant actions more frequently.³⁸ The number of Administrative Law Judges increased from 2 in 2008 to 3 by 2012, and the number of attorneys in the Diversion Litigation Section increased from 5 attorneys in 2006 to 12 in 2013.³⁹

³⁶ We discuss the role of the Diversion Litigation Section in forwarding cases to the Office of the Administrator further below.

³⁷ Included in the averages for the entire adjudicative process is the time from when a registrant action is issued to when the Diversion Litigation Section becomes aware that it will be responsible for forwarding the registrant action to the Office of the Administrator. This may happen because the deadline has passed for the registrant to request a hearing and the registrant has not done so, because the registrant formally waived a hearing, or because an ALJ terminated the proceedings. The average amount of time in this stage of the adjudication was 72 days in 2008 and 55 days in 2012.

³⁸ We further discuss a shift in DEA enforcement operations and its impact on the adjudication of registrant actions below.

³⁹ The Chief ALJ told us that a third ALJ was added to the Office of Administrative Law Judges in 2009 because delays in issuing recommended decisions were increasing. The Chief ALJ also told us that the Office of Administrative Law

(Cont'd.)

We also found that the Chief ALJ issued internal policies and training to ensure the timely processing of registrant actions. In addition, Diversion Litigation Section Chiefs directed attorneys in the section to limit their requests for continuances during the hearing process.

Office of Administrative Law Judges' Efforts to Improve Timeliness

Our review of DEA data showed that the Office of Administrative Law Judges' timeliness in the adjudication process has improved since the current Chief ALJ was promoted to that position in 2010. For example, the timeliness of registrant actions from initiation of an order to when the Office of Administrative Law Judges forwarded an ALJ's recommended decision to the Office of the Administrator decreased from an average of 570 days in 2010 to an average of 241 days in 2012, an improvement of 10 months.

We found that the Chief ALJ instituted internal policies and training designed to hold staff accountable for the timely processing of registrant actions. For example, in February 2011, in response to an increased workload, the Chief ALJ issued a memorandum to "ensure accountability and to clarify lines of staff responsibility." Within the memorandum, the Chief ALJ stated that, "one of the fundamental functions of [the Office of Administrative Law Judges] is to keep cases moving efficiently and accurately through the system towards a recommended decision . . . or to some other permanent solution." The Chief ALJ also established an Office of Administrative Law Judges Central Staff in May 2012 responsible for "ensuring that cases, communication, and documents move efficiently and accurately through the system to facilitate an expeditious recommended decision." In addition, the Chief ALJ created training materials for new ALJs and Office of Administrative Law Judges staff, including an orientation manual that includes guidance on drafting orders and opinions, prehearing conferences, and hearing preparation.

Diversion Litigation Section Efforts to Improve Timeliness

We found Diversion Litigation Section Chiefs directed the section's attorneys to restrict the number of requests for continuances.⁴⁰ The

Judges hired a fourth ALJ during the scope of the OIG's review, but the ALJ had to retire unexpectedly.

⁴⁰ We could not confirm a trend of decreased continuance requests on the part of Diversion Litigation Section attorneys through analysis of the registrant action data. Continuances were requested by the DEA's attorneys in 20 percent of registrant actions

(Cont'd.)

ALJs also told us that they believe Diversion Litigation Section attorney requests for continuances were more limited today than in the past. The Chief ALJ, who joined the Office of Administrative Law Judges in 2009, said that Diversion Litigation Section attorneys requested fewer continuances than they used to in his cases and they provide better justifications for the continuances they do request.

Delays in the adjudication process adversely affect the DEA, registrants, and public.

The DEA established its process to adjudicate registrant actions to protect public health and safety from imminent threats posed by the misconduct of registrants. Given these public health and safety concerns, it is essential that the process to adjudicate registrant actions be timely. The DEA further articulated the importance of a timely adjudication process, particularly for those registrants issued an immediate suspension order, by stating in the 2006 memorandum that a prompt post-deprivation hearing and decision are required by the due process clause of the Constitution. Regarding orders to show cause, both past and present DEA officials said the impacts of delays in the adjudication process are twofold: noncompliant registrants could continue prescribing drugs, while compliant registrants could go out of business. Throughout our review, DEA officials and staff provided us with examples of adverse effects from delays in the adjudication of registrant actions not only on the public and the registrants, but on the DEA itself. Below we discuss some of these adverse effects.

Delays in the adjudication of registrant actions create risks to public health and safety.

Although the public is not directly involved in the adjudication of registrant actions, DEA staff and officials we spoke to said that the public still has a vested interest in the timely resolution of all orders to show cause and immediate suspension orders. For example, an ALJ noted that registrants whose registrations should be revoked put people at risk. Delays in the adjudication of registrant actions expose the public to health and safety threats posed by the misconduct of registrants. The Chief ALJ also told us that if a doctor is issued an order to show cause, that doctor can keep writing diverted prescriptions until the DEA makes a final decision. In such cases, particularly if there is no immediate

that reached final decision throughout our scope. However, the adjudication process often spanned more than 1 year, and our analysis was able to capture only the total number of continuance requests per registrant action rather than the specific year in which each continuance request was made.

suspension order, a timely adjudication process is essential to protecting public health and safety.

A registrant's livelihood, career, and ability to do business are affected by delays in the adjudication process.

A former Diversion Litigation Section Chief described the effect of delays in the adjudication of registrant actions as, "justice delayed is justice denied." Current DEA staff and officials told us that delays in the adjudication of registrant actions not only raise due process concerns, as discussed above, but that registrants who are engaged in legitimate business practices face additional harms. For example, doctors who lack controlled substance prescribing authority as a result of an immediate suspension order cannot fully practice medicine unless the order is lifted, which affects their professional livelihood, can cause financial losses and hardship on their families, can harm their reputation, and can affect whether their claims are accepted by their patients' insurance companies.⁴¹

Several DEA employees we interviewed noted that the detrimental impact on registrants of the uncertainty created by the adjudication process is accentuated when the process is unnecessarily delayed. The Diversion Litigation Section Chief said that, when there are delays in the adjudication of registrant actions, a registrant is "in limbo." A Diversion Litigation Section attorney similarly noted that registrants encounter "uncertainty" because, even though registrants who are served with an order to show cause can still practice, the issues are unresolved. The attorney said a registrant's business potential could completely change when a final decision is delayed. Another Diversion Litigation Section attorney said the impact of delays is worse for registrants with pending applications who are served with an order to show cause because they do not have a registration yet, which can impede their practice of medicine. In our review of final decisions, we found examples of such delays both in cases where the applicant was eventually granted a registration and was able to open a practice and in cases where the applicant's registration was eventually denied. Specifically, one applicant testified in her hearing that she had suspended her job search because most "of the positions I have sought require a DEA [registration] or else eligibility within a year" and she did not know how long the adjudication process would take. The Administrator granted this applicant a new registration 9 months after the hearing.

⁴¹ A former Diversion Litigation Section Chief told us that most medical insurance carriers require practitioners to hold a registration before they will accept a claim.

The effects of delays in the adjudication process on the DEA include mission failure, evidence becoming stale, and decreased employee morale.

The DEA's mission includes protecting the public and enforcing federal drug laws. DEA officials and staff told us that delays in the adjudication of registrant actions create the risk to the DEA and public that registrants may not stop their criminal behaviors, particularly in cases where the registrant is not served an immediate suspension order and therefore can continue treating patients.

In addition, DEA officials and staff had concerns regarding legal issues that can result from delays in the adjudication of registrant actions. For example, delays in the adjudication of registrant actions result in evidence used to support a registrant action becoming old, or "stale." A Diversion Litigation Section attorney described the impact of a final decision that she described as "stale." She told us about a final decision where the Administrator dismissed the case after a 1-year wait could be affected by that delay because if the case is re-charged all of the evidence will be more than a year old. The Administrator's Attorney Advisor told us about another case where he described the evidence against a doctor who was the subject of an immediate suspension order as very stale. In that case, the Court of Appeals took note of the DEA's lengthy adjudication, even though the court upheld the DEA's final decision.

Finally, some DEA employees we interviewed noted that delays in the adjudication of registrant actions can affect employee morale and harm public perception. For example, one ALJ told us that DEA field agents, such as Diversion Investigators, get frustrated by delays, leading to lower morale, and a former Diversion Litigation Section Chief said delays make the DEA appear inefficient to the public and the regulated community.

Enforcement operations and administrative procedures can affect the timeliness of issuing final decisions.

We found several factors in the DEA's process to adjudicate registrant actions, as well as its diversion enforcement efforts, that can substantially affect the timeliness of final decisions. First, the caseload of registrant actions has increased due to diversion enforcement efforts. Second, immediate suspension orders are expedited and take priority over other registrant actions. Third, there are variations between ALJs in how they prefer to manage their caseloads. Fourth, there are no procedures or timeliness standards for the Diversion Litigation Section to forward registrant actions adjudicated solely by the Administrator to the

Office of the Administrator. Fifth, all registrant actions are reviewed twice within the Office of the Administrator prior to the Administrator's final decision. Finally, the DEA cannot effectively determine the time it takes to adjudicate each registrant action through final decision. Overall, we found that each of these issues represents an area where the DEA could assess its procedures and operations to determine whether appropriate changes could be effected to improve its overall timeliness of the adjudication of registrant actions.

The DEA's diversion enforcement operations have increased the caseload of registrant actions.

In recent years, the DEA has devoted more resources to preventing the diversion of prescription drugs for illegitimate purposes, which has led to an increase in the number of registrant actions initiated, a larger adjudicative workload, and a corresponding increase in the number of final decisions issued. Specifically, we found the number of immediate suspension orders that were initiated increased 71 percent throughout our scope, from 24 in 2008 to 41 in 2012, reaching a high of 65 in 2011. In addition, while 50 orders to show cause were issued in both 2008 and 2012, orders to show cause ranged from 74 in 2009 to 66 in 2011. The Administrator and the Deputy Chief Counsel told us that the DEA issued more registrant actions due to a shift in diversion enforcement strategies focused on three emerging threats to public health and safety: internet pharmacies, "pill mills," and wholesale distributors.⁴² The Deputy Chief Counsel added that with registrant actions issued to address these emerging threats there was a learning curve on the best way to litigate the cases, which could have affected the timeliness of the adjudication process.

Additionally, the Deputy Chief Counsel and Diversion Litigation Section Chief stated that the decrease in the number of registrant actions initiated in 2012 can also be attributed to the previously mentioned increased volume of cases against manufacturer and distributor registrants that began in 2006. They said that when the DEA began focusing registrant actions against large, wholesale distributors rather than simply "rounding up" individual pain clinic practitioners, fewer registrant actions were issued, although those that were issued were more complicated and time-consuming to litigate.

⁴² "Pill mills" are medical clinics (sometimes called pain management clinics) that distribute without a legitimate medical purpose large amounts of controlled substances such as painkillers or anti-anxiety medications to patients. The drugs are often dispensed without a complete medical exam or a clear diagnosis.

We also found that more complicated cases against large distributors are more likely to result in multiple actions that are then consolidated into a single case, which can result in delays in issuing final decisions. The Diversion Litigation Section Chief told us that consolidating cases can also lead to delays. He said that, for example, large corporations hold multiple registrations and sometimes in charging these companies, the DEA will issue orders to show cause on two to three of the company's registrations, then serve additional orders to show cause on additional registrations as an investigation develops. The Chief ALJ agreed that this practice can lead to delays for the original order to show cause because federal law dictates that multiple cases arising from the same pattern of facts should be consolidated to ensure consistent decisions. Furthermore, DEA personnel said that negotiating settlements in cases that do not result in a final decision can contribute to delays in the adjudication of other registrant actions that may result in a final decision. For example, when the registrant and the DEA pursue settlement discussions during the adjudicative process, they may file prehearing statements and hold prehearing conferences before coming to a settlement agreement and asking the ALJ to terminate the proceedings. While settlements mean that the ALJ does not have to devote time to holding a hearing or writing a recommended decision, the ALJ must still hold prehearing conferences and review documents that the parties file before they request termination. These activities take time that is no longer available for the ALJ to devote to registrant actions that are not settling and will require hearings and recommended decisions. Settlement negotiations may also keep attorneys from forwarding other registrant actions to the Administrator when the registrant does not request a hearing.

Immediate suspension orders are expedited over other cases.

Officials and staff in the Office of Administrative Law Judges, the Diversion Litigation Section, and the Office of the Administrator told us that when a registrant is issued an immediate suspension order and requests a hearing, staff will prioritize the matter over other pending registrant actions. For example, an ALJ stated that immediate suspension orders, which raise due process concerns, "go to the head of the line when they come in." Similarly, the Administrator said that she prioritizes immediate suspension orders over other cases, which may result in cases that require little legal analysis being set aside and not completed so that immediate suspension orders can be adjudicated first.

DEA staff also told us that it can be difficult to prioritize immediate suspension orders and still meet the timeframes in the 2006 memorandum, particularly when numerous immediate suspension orders are issued in a short period of time. The Administrator told us

that when the 2006 memorandum was issued, the DEA was initiating only 5 or 6 immediate suspension orders a year, whereas our review found that immediate suspension orders represented 32 percent of all registrant actions initiated in 2008 (24 of 74) and 45 percent of all registrant actions initiated in 2012 (41 of 91).

ALJs vary in how they conduct proceedings.

ALJs have discretion in setting initial dates and deadlines for prehearing briefs, responses to motions, exhibit filings, status reports on stays granted, hearings, and post-hearing briefs. Our review of docket sheets found that ALJs varied in the time it took them to complete the three major stages of registrant actions in which the registrant requested a hearing: (1) the pre-hearing stage; (2) the post-hearing stage; and (3) the post-decision stage. We found that the average time, by ALJ, for the pre-hearing stage ranged from 120 days to 219 days – a difference of over 3 months. One ALJ averaged 43 days for the post-hearing stage, whereas another ALJ averaged 302 days – a difference of over 8 months. Table 2 shows the individual ALJs' average number of days to complete each of the three stages under their jurisdiction from 2008 through 2012.

Table 2: Average Timeliness of ALJs from Hearing Request to Recommended Decision, 2008 through 2012

ALJ	Average Days for Pre-hearing Stage	Average Days for Post-hearing Stage	Average Days for Post-decision Stage
A	120	43	33
B	134	88	33
C	146	282	42
D	219	302	47

Note: We excluded one ALJ who presided over only one case that resulted in a final decision.

Source: OIG analysis of Office of Administrative Law Judges docket sheets.

The DEA does not have procedures or timeliness standards for managing cases adjudicated solely by the Administrator.

We found that the DEA does not have procedures or timeliness standards for forwarding registrant actions to be adjudicated solely by the Administrator to the Office of the Administrator for a final decision. Registrants have 30 days after being served with an order to show cause

or an immediate suspension order to submit a request for a hearing to the Office of Administrative Law Judges.⁴³ If a registrant requests a hearing, the regulations specify that the Office of Administrative Law Judges should provide the case to the Office of the Administrator for a final decision no less than 25 days from when the ALJ issues the recommended decision.⁴⁴ However, the regulations do not specify a process or timeliness standards for providing cases to the Office of the Administrator for a final decision when the registrant does not request a hearing, misses the deadline to request a hearing, waives the right to a hearing, or an ALJ terminates hearing proceedings without issuing a recommended decision.⁴⁵ In such cases, Diversion Litigation Section attorneys are responsible for preparing a summary of the DEA's argument as to why a registration should be revoked, compiling exhibits and other evidence to support that argument, and forwarding those materials to the Office of the Administrator for a final decision.

Between 2008 and 2012, the average time Diversion Litigation Section attorneys took to prepare these materials was 98 days. While the Diversion Litigation Section Chief told us that it is "fairly rare" for a registrant not to request a hearing after being served with an order to show cause or an immediate suspension order, we found that registrant actions adjudicated solely by the Administrator represented 34 percent (61 of 178) of all registrant action final decisions issued between 2008 and 2012.

We found no formal guidance regarding registrant actions without a request for a hearing, including timeliness standards for forwarding these cases or guidance stating which case materials are to be forwarded to the Office of the Administrator. Specifically, we found that the Diversion Litigation Section attorneys had self-imposed timeframes to forward registrant actions to be adjudicated solely by the Administrator to the Office of the Administrator, and those timeframes varied. For example, one Diversion Litigation Section attorney said that the Diversion Litigation Section has no formal expectations for how quickly she prepares and forwards case materials to the Office of the

⁴³ 21 C.F.R. § 1301.43(a).

⁴⁴ 21 C.F.R. § 1316.65(c).

⁴⁵ Under 21 C.F.R. § 1301.43(d)-(e), if the registrant or applicant fails to request a hearing, or fails to appear at the hearing requested by the registrant or applicant, the registrant or applicant is considered to have waived the opportunity for a hearing, unless good cause can be shown for the failure to request a hearing or appear at the requested hearing. If all parties entitled to a hearing are deemed to have waived that hearing, the Administrator may cancel the hearing and issue a final decision without a hearing.

Administrator, but her personal goal was to submit the materials no more than 6 weeks after the registrant's failure to request a hearing. Another attorney told us her goal was 30 days. We also found that the Diversion Litigation Section did not have any written guidance on what information to include in the materials forwarded to the Office of the Administrator. Diversion Litigation Section attorneys told us that they included all of the evidence that they would have presented at a hearing if the registrant had requested one. A former Diversion Litigation Section Chief we interviewed noted that the decision about what materials are provided to the Administrator is important, as those materials would, in the case of an appeal, be provided to the court as the basis for the DEA's decision.

The Deputy Chief Counsel said that delays in forwarding registrant actions adjudicated solely by the Administrator were likely because Diversion Litigation Section attorneys had a lot of work that was both time-sensitive and contested, and requests for final decisions were neither. He added that if a registrant effectively conceded and elected not to avail itself of the DEA's adjudication procedures, it was not surprising that Diversion Litigation Section attorneys would deem work on such registrant actions a low priority relative to their other responsibilities.

The Office of the Administrator's review averages 162 days (more than 5 months) for registrant actions in all categories.

According to the DEA's 2006 memorandum, for immediate suspension orders the goal is to issue a final decision within 180 days. As specified in the 2006 memorandum, the Office of Administrative Law Judges is required to submit the certified record and a recommended decision to the Office of the Administrator no more than 150 days after an immediate suspension order is issued, thereby providing the Office of the Administrator 30 days to issue a final decision. As stated earlier, we found that the average number of days the Office of the Administrator took to issue final decisions for immediate suspension orders exceeded 30 days in all but one immediate suspension order where an ALJ issued a recommended decision. Specifically, between October 2010 and the end of 2012, the Office of the Administrator averaged 175 days to review immediate suspension orders, which is nearly the amount of time the 2006 memorandum envisioned for the entire adjudicative process.

We found that when registrant action cases are received in the Office of the Administrator they are reviewed first by an Attorney Advisor who reads the entire file and drafts a proposed final decision either agreeing with the ALJ's recommended decision or modifying it, and then by the Administrator, who reviews the Attorney Advisor's proposal and

makes the final decision.⁴⁶ The Attorney Advisor told us that a number of factors, such as the physical length of a case file, can affect how long it takes the Office of the Administrator to review a registrant action and issue a final decision.

The Attorney Advisor told us that since October 2010 he has used a spreadsheet to track the progress of registrant actions once they are received by the Office of the Administrator. We reviewed the Attorney Advisor's spreadsheet and found that the Attorney Advisor's review of the case file and the Administrator's review of the proposed final decision averaged between 36 days and 126 days each, respectively, depending on the type of case. As a result, the Office of the Administrator averaged 175 days to review immediate suspension orders.⁴⁷ For orders to show cause and cases adjudicated solely by the Administrator, where the DEA has not imposed any timeframes, the Office of the Administrator averaged between 150 and 162 days to issue final decisions (5 months). See Table 3 for the average number of days for the Attorney Advisor's review and the Administrator's review of registrant actions from October 2010 to December 2012.

⁴⁶ After reviewing a working draft of this report, the DEA emphasized that the review within the Office of the Administrator is a single review involving consultation between the Administrator and the Attorney Advisor, not two sequential reviews. Nevertheless, because the data provided to us by the DEA tracked the dates for the Attorney Advisor's and the Administrator's reviews separately, and because the process was presented to us during interviews with DEA personnel as a two-stage review, we have assessed the timeliness of the Administrator and Attorney Advisor both separately and together in this report.

⁴⁷ In 3 of the 17 immediate suspension orders decided between October 2010 and December 2012, the Administrator's review took more than 10 months, which is why her average review time for immediate suspension orders was 110 days. If these three cases were excluded, her average review time for immediate suspension orders would have been 63 days.

Table 3: Average Days for the Attorney Advisor's Review and the Administrator's Review of Registrant Actions, October 2010 to December 2012

	Attorney Advisor's Average Days	Administrator's Average Days	Total Average Days
All Cases (61)	102	60	162
Orders to Show Cause (24)	126	36	162
Immediate Suspension Orders (17)	65	110	175
Adjudicated Solely by Administrator (20)	104	47	150

Notes: Averages for cases adjudicated solely by the Administrator do not add up due to rounding.

For our analysis, we examined only cases that were published in the *Federal Register* by the end of 2012.

Source: OIG analysis of Attorney Advisor's tracking spreadsheet.

The DEA cannot effectively determine the time it takes to adjudicate each registrant action through final decision.

We found that the DEA has never analyzed the timeliness of the adjudication of registrant actions, whether its adjudication of registrant actions is timely and in compliance with its own policy, or where delays occur in the adjudication process. In addition, we found that the DEA maintains at least three different case tracking systems for registrant actions, none of which tracks all of the major events for each registrant action that results in a final decision. Specifically:

- Office of Administrative Law Judges' Case Management System: The Case Management System tracks all registrant actions where a registrant requests a hearing and the case is assigned to an ALJ. According to the DEA, the Case Management System has limited functionality because it is not designed for analysis and does not contain information on deadlines. We found the Case Management System allowed the Office of Administrative Law Judges to create docket sheets to organize and maintain all of the documents filed in each case.⁴⁸ Office of Administrative Law Judges employees told us that the system tracks whether continuances were granted in a case, but because the system does not maintain information about deadlines, it cannot report on the extent to which those continuances affected a case's timeliness. Also, because the

⁴⁸ The Chief ALJ provided the OIG with a brief demonstration of the Case Management System capabilities, and screenshots, on May 22, 2013.

system lacks deadline information, Office of Administrative Law Judges staff uniformly told us that they do not rely on it for case tracking, and that they instead rely on weekly, hardcopy narrative case status updates for this purpose.

- Diversion Litigation Section’s Case Tracker: From approximately 2006 to late 2010, the Diversion Litigation Section maintained a case management system called Case Tracker, which tracked all registrant actions initiated and whether they resulted in a final decision. We reviewed a screenshot of Case Tracker and found that it could track the dates registrant actions were initiated and the dates that certified case files were forwarded to the Office of the Administrator for a final decision. However, Case Tracker was replaced with a new system called ProLaw in March 2012.⁴⁹ The Deputy Chief Counsel stated that determining the average time of each registrant action at each stage of the process could be done using ProLaw on a case-by-case basis, but not automatically. Diversion Litigation Section attorneys, however, noted that it is their responsibility to add information to ProLaw, and they did not know if all of the attorneys in the section recorded all of the dates associated with every case.
- Office of the Administrator Spreadsheet: The Administrator’s Attorney Advisor tracks all registrant actions that are provided to the Office of the Administrator for a final decision using a spreadsheet. We reviewed this spreadsheet and found that it tracks when registrant actions are forwarded to the Office of the Administrator and when the Administrator signed a final decision, including the dates of the Attorney Advisor’s review of each registrant action before it is signed by the Administrator. However, the Attorney Advisor’s spreadsheet does not track earlier stages in the process, and it does not contain data for events occurring prior to October 2010.

Overall, the DEA’s use of multiple case tracking systems prevents it from tracking each registrant action in its entirety. We found that none of the current case management systems offers a convenient, automated way to track all of the registrant actions as they progress through the entire adjudication process.

⁴⁹ The Diversion Litigation Section provided a screenshot to the OIG of the ProLaw database. We found that ProLaw reports active registrant actions by attorney and tracks the dates of key case events, including when a charging document was issued, when a recommended decision was issued, when a case was forwarded to the Office of the Administrator, and when a final decision was issued.

In addition to the weaknesses in case management systems, we also found that no individual or office within the DEA monitors the progress of each case throughout the adjudication process. Both the Chief ALJ and the Diversion Litigation Section Chief said that only the Administrator has the broad authority to monitor the progress of registrant actions throughout the whole adjudication process. The Administrator told us that through a new Docket Master System being implemented in the Office of Administrative Law Judges, she anticipates being able to see how long registrant actions take from start to finish, why registrant actions are delayed, and which registrant actions are upcoming.⁵⁰

Recent actions taken by the DEA may improve the timeliness of the adjudication process.

We found that the DEA has taken steps to facilitate the adjudication of registrant actions, which the DEA believes will improve the timeliness of the hearing process and the issuance of final decisions. For example, the Office of Administrative Law Judges has moved into new facilities with multiple courtrooms that are equipped with video teleconferencing capabilities. Also, in addition to the Administrator, the Deputy Administrator has begun reviewing cases and issuing final decisions. Finally, the Office of Administrative Law Judges is developing a new case management system that the DEA hopes to eventually make accessible to all personnel involved in the adjudication process to improve the DEA's case tracking abilities.

New Office of Administrative Law Judges courtrooms may improve the timeliness of the hearing process and provide cost savings.

The regulations require that hearings take place at the date and the time stated in the order to show cause or the immediate suspension order. However, the Administrative Procedure Act states that administrative hearings should be set with regard to the convenience of the parties.⁵¹ Additionally, the subpoena authority for the Controlled Substances Act is limited to witnesses who are within 500 miles of the hearing location.⁵² Due to this geographical limitation on subpoenas authorized under the Controlled Substances Act, as well as due process

⁵⁰ We discuss the new Docket Master System further below.

⁵¹ 5 U.S.C. § 554(b).

⁵² 21 U.S.C. § 876.

concerns, hearings have traditionally been conducted near the registrant's principal place of business.⁵³

In 2012, the Office of Administrative Law Judges began using video teleconferencing for hearings. According to the DEA, courtrooms equipped with video teleconferencing technology at the Office of Administrative Law Judges will save time and costs associated with the ALJs' cross-country travel by allowing live testimony to be given from other locations. Based on our review of DEA data, we found that the DEA spent approximately \$5 million on testimony and hearing proceedings for the Office of Administrative Law Judges, the DEA's Office of Chief Counsel, and other DEA personnel from 2008 through 2012. See Table 4 for costs associated with DEA testimony and hearing proceedings from 2008 through 2012.

Table 4: Costs Associated with DEA Testimony and Hearing Proceedings, 2008 through 2012

Year	Headquarters	Field Offices	Total
2008	\$148,771	\$254,201	\$402,972
2009	\$276,361	\$452,853	\$729,214
2010	\$315,795	\$607,528	\$923,323
2011	\$442,171	\$1,179,040	\$1,621,211
2012	\$302,433	\$992,307	\$1,294,740
Total	\$1,485,531	\$3,485,929	\$4,971,460

Notes: Headquarters includes the Office of Administrative Law Judges, Office of Chief Counsel, Operations Division, and Operational Support Division. Field office expenditures include domestic and foreign field offices.

Costs include testimony, expert witnesses, trial preparation, transcription, and associated travel and lodging. DEA employee labor costs are not included.

Source: DEA.

The Administrator said that she prefers that hearings be held at the Office of Administrative Law Judges because it cuts down on travel and the time lost on other matters due to traveling. The Chief ALJ also said that while the system is too new to determine any cost savings from

⁵³ The Chief ALJ told us that the Office of Administrative Law Judges conducts hearings in remote locations where various federal and state agencies have been able and willing to make their courtrooms available for this purpose. The DEA has conducted remote hearings in United States Tax and Bankruptcy Courts, United States District and Circuit Courts, various state and local courts, as well as in courtrooms loaned by federal agencies such as the National Labor Relations Board and the United States Immigration Court.

video teleconferencing, he believes that video teleconferencing will reduce travel expenses, allow the ALJs to complete their other work more efficiently due to less time lost while on the road, and save time for the Office of Administrative Law Judges' Hearing Clerk, who otherwise must devote extensive time to finding and reserving courtrooms in other locations. He also said video teleconferencing will help registrants and other witnesses by not requiring them to take time away from their jobs to travel to a hearing.

However, some DEA employees acknowledged issues that must be addressed in implementing video teleconferencing for registrant actions. Specifically, the Chief ALJ said video teleconferencing involves certain challenges with managing a proceeding from a distance and that the parameters set by the Administrative Procedure Act and Controlled Substances Act raise due process concerns that an ALJ must consider when scheduling hearings, including determining whether a hearing can take place using video teleconferencing or whether the ALJ needs to travel and conduct the hearing personally. Another ALJ stated that if there are issues with the registrant's credibility, the ALJ may prefer to see the registrant in person.

The Deputy Administrator is now reviewing cases and issuing final decisions.

During the scope of our review, the current Administrator made all final decisions about registrant actions, first in her role as Deputy Administrator and later as Acting Administrator then permanent Administrator. The Administrator said that the responsibility for issuing final decisions was not immediately delegated to the current Deputy Administrator because at the time of the Deputy Administrator's confirmation, the DEA did not have an Operations Chief and the current Deputy Administrator therefore functioned as the Operations Chief when he was first confirmed.⁵⁴ The Administrator further said that when functioning as the Operations Chief, the Deputy Administrator was also the first-line supervisor for the Office of Diversion Control, which created a potential conflict of interest in serving as the final decision-maker for the adjudication of registrant actions generated by the Office of Diversion Control. The appearance of this conflict delayed the Deputy Administrator's involvement in issuing final decisions until a new Operations Chief was selected.

In January 2013, the DEA selected a new Operations Chief, which allowed the Deputy Administrator to function solely in that capacity and

⁵⁴ The Deputy Administrator was confirmed on March 29, 2012.

removed the conflict. The Administrator told us that she anticipates that both she and the Deputy Administrator will share the responsibility for signing final decisions in the future, with the Deputy Administrator assuming responsibility for signing final decisions in orders to show cause where the registrant has no state authority to handle controlled substances. The Administrator said that she anticipates that the process for issuing final decisions will be both “smoother” and more timely in the future with both her and the Deputy Administrator signing final decisions.⁵⁵

A new case management system may improve and unify the tracking of registrant actions.

As discussed above, the Office of Administrative Law Judges, the Diversion Litigation Section, and the Office of the Administrator each had its own case management system to track the progress of registrant actions throughout the adjudication process. The Office of Administrative Law Judges is now working with the DEA Office of Information Systems to test and implement a new database for case tracking called the Docket Master System.⁵⁶ The DEA stated that the Docket Master System will allow increased monitoring of the case flow to isolate and address any “choke points” to improve efficiency.

The Chief ALJ stated that the Docket Master System was designed specifically to address the weaknesses in the Case Management System described above.⁵⁷ He added that the Docket Master System will show the length of continuances, not just whether they were granted, and that it will facilitate overall oversight of the adjudication process. Another ALJ told us that the Docket Master System was developed because the old system, the Case Management System, was not responsive to the

⁵⁵ As of April 7, 2014, the Deputy Administrator had issued 11 final decisions, including 7 in 2013 and 4 in 2014.

⁵⁶ In response to a working draft of this report, the DEA stated, “The problematic Case Management System has been replaced with a new case tracking system called the Docket Master System. With the Docket Master System, the Office of the Administrative Law Judges now has the capacity to capture and run reports on case milestones, and this allows the assessment of ‘choke points’ in the process to improve efficiency.”

⁵⁷ On May 7, 2013, the OIG met with officials and staff from the Office of Administrative Law Judges, the DEA’s Office of Chief Counsel, and the Office of the Administrator. At this meeting, the Chief ALJ told the OIG that the Docket Master System was being launched on the same day. In response to a working draft of this report, the DEA stated that use of the Docket Master System began on schedule and that after several months of testing and modifications, the Docket Master System would supplant the Case Management System before March 31, 2014.

Office of Administrative Law Judges' needs and did not track what the ALJs needed to track.

The Administrator told us that through the Docket Master System she anticipates being able to see how long cases take from start to finish, why cases were delayed, and what cases are upcoming. She added that initially only the Office of Administrative Law Judges will have access to the new system due to the cost of expanding access to multiple DEA offices, but that she hopes that the Office of the Administrator, as well as the Diversion Litigation Section, will eventually have access to the Docket Master System.

CONCLUSION AND RECOMMENDATIONS

While the DEA's process to adjudicate registrant actions and issue final decisions is compliant with applicable laws and regulations, these laws and regulations do not include timeliness standards for the entire adjudication process. We found that the DEA does not have timeliness standards that apply to the entire adjudication process or to all types of registrant actions and that the time it takes the DEA to reach a final adjudication is, on average, very lengthy. The average number of days the DEA took to make a final decision ranged from a high of 730 days in 2009 to 366 days in 2012. Even in cases involving immediate suspension orders, the one area where the DEA has put in place a timeliness goal, the DEA does not come close to meeting its goal of 180 days to final adjudication. While the timeliness to adjudicate immediate suspension orders has improved, in 2008 immediate suspension orders took more than a year and a half on average to adjudicate, and by 2012 they still took more than a year on average to adjudicate. We found that the Office of the Administrator's review alone took an average of 231 days in 2008 and an average of 185 days in 2012. While we found that the overall time it takes the DEA to adjudicate registrant actions continues to be very lengthy, the timeliness of the adjudication process nevertheless comports with the applicable laws and regulations, which do not include specific timeliness standards.

DEA officials and staff we interviewed identified adverse effects that can result from delays in the adjudication of registrant actions. For example, DEA staff told us that delays in the adjudication of registrant actions diminish the DEA's ability to protect the public from imminent threats to health and safety arising from registrants' misconduct. In addition, delays can be detrimental to registrants' careers, and subsequently, their livelihood and ability to provide for their families.

We identified several factors that contributed to the length of the DEA's adjudication proceedings. In some cases, delays resulted from actions commonly associated with most administrative litigation proceedings, such as negotiating settlements or variations between ALJs in how they prefer to manage their caseloads. However, in other cases, we found delays can result from a lack of guidance or from the process the DEA uses to issue final decisions. For example, Diversion Litigation Section attorneys are responsible for forwarding registrant actions to the Office of the Administrator for a final decision if the registrant does not request a hearing, but we found no guidance applicable to this responsibility. As a result, each Diversion Litigation Section attorney we

interviewed had different self-imposed timeliness standards for forwarding registrant actions to the Office of the Administrator.

The DEA has taken steps that it believes will improve the timeliness of the adjudication of registrant actions in the future. However, we believe more can be done to improve the timeliness of the adjudication of registrant actions and ensure adverse effects of delays are mitigated, including establishing oversight of the adjudication of registrant actions through the Office of the Administrator and expanding the use of the DEA's new Docket Master System.

Recommendations

We make the following three recommendations to improve the DEA's ability to effectively and efficiently adjudicate all registrant actions in a timely manner and mitigate the potential adverse effects of delays on the DEA, registrants, and the public. We recommend that the DEA:

1. Establish timeliness guidelines for adjudicating all orders to show cause.
2. Establish policy and procedures, including timeliness guidelines, for forwarding a case to the Office of the Administrator for final decision when a hearing is waived or terminated.
3. Institute a formal process for tracking the timeliness of each adjudication from the initial registration action to the DEA's final decision and for periodically assessing timeliness.

APPENDIX I: SCOPE AND METHODOLOGY OF THE OIG REVIEW

We examined the DEA's process for issuing final decisions on registrant actions from the issuance of an order to show cause or immediate suspension order to the issuance of a final decision from calendar years 2008 through 2012. We examined federal laws and regulations, as well as the DEA's policies and procedures for the adjudication of registrant actions and issuance of final decisions. We also analyzed the timeliness of the adjudication of registrant actions, including the Office of the Administrative Law Judges' timeliness in issuing recommended decisions, and the timeliness of the Administrator in issuing final decisions. In addition, for registrant actions that did not include an ALJ's recommended decision, we analyzed the timeliness of the Diversion Litigation Section in forwarding registrant actions to the Office of the Administrator for a final decision. Lastly, we assessed the impact of any delays by the DEA in the adjudication process on registrants and the public.

Our fieldwork, conducted from May 2013 through August 2013, included interviews, document analysis, and data collection and analysis. The following sections provide additional information on the methodology of our review.

Interviews

We interviewed 21 DEA officials and staff with roles in the adjudication of registrant actions. In the Office of the Administrative Law Judges, we interviewed three ALJs, including the Chief Administrative Law Judge. We also interviewed one former ALJ who adjudicated DEA registrant actions during the scope of our review. In addition, we interviewed the Office of the Administrative Law Judges Hearing Office Director, Hearing Clerk, two secretaries, and three law clerks. In the DEA's Office of Chief Counsel, we interviewed the Deputy Chief Counsel, the Associate Chief Counsel (Section Chief) for the Diversion Litigation Section (twice), and three Diversion Litigation Section trial attorneys. We also interviewed two former Diversion Litigation Section Chiefs who supervised Diversion Litigation Section trial attorneys during the scope of our review. In the Office of the Administrator, we interviewed the Administrator (twice) and the Administrator's Attorney Advisor.

In addition, at the outset of our fieldwork, we met collectively with DEA representatives from each office involved in the adjudication of registrant actions to discuss the role of each office and its staff in the process, as well as to discuss applicable policies or guidance and data

maintained on all registrant actions. DEA representatives at this meeting included an Executive Assistant from the Office of the Administrator; the Deputy Chief Counsel and Associate Chief Counsel/Diversion Litigation Section Chief; the Office of the Administrative Law Judges' Chief ALJ and Hearing Office Director; an Executive Assistant from the Office of Diversion Control; and seven representatives from the Office of Inspections.

Document Analysis

We reviewed the laws, regulations, and legislative history governing the adjudication of registrant actions, including the *Administrative Procedure Act of 1946* and the *Controlled Substances Act of 1970* and its associated regulations. We also reviewed DEA policies on the processing and adjudication of registrant actions and training materials discussing the adjudication process that were prepared for new employees in the Office of Administrative Law Judges and the Diversion Litigation Section.

Data Analysis

Our analysis included the collection of dates for key events in the adjudication process for each registrant action that resulted in a final decision. We analyzed the timeliness of the adjudication process as a whole, as well as the timeliness between key events (stages of the adjudication process) and the timeliness of each office that had a role in the adjudication of registrant actions. Examples of key events include the date an order to show cause or immediate suspension order was issued, the date a hearing began, the date an ALJ issued a recommended decision, and the date the Administrator issued a final decision. We also used published final decisions to collect data on the type of registrant (retail or wholesale), the type of order issued (order to show cause or immediate suspension order), the action recommended by an ALJ, and the action taken by the Administrator. We did not assess the substantive basis for final decisions.

We conducted a review of all orders to show cause and immediate suspension orders with and without a hearing that resulted in a final decision by the Administrator from 2008 through 2012. We did not address the role of the DEA's Office of Diversion Control prior to issuance of one of these orders or in serving orders on registrants. Our analysis used the date of issuance of an order to show cause or immediate suspension order as the beginning point in calculating timeliness rather than the date orders were served because the 2006 memorandum established that timeliness standards for immediate suspension orders began at the issuance of the order, not at service of the order. Because

there are no timeliness standards for orders to show cause, we used the same starting point to ensure our analysis of both types of orders was consistent and comparable.

We obtained all published final decisions from the DEA's Office of Diversion Control website.⁵⁸ However, the published decisions did not consistently include all of the data we sought to analyze, including the date a charging document was issued, the date a hearing was held, and the date a case was forwarded to the Office of the Administrator. To obtain missing data, we requested and received data from multiple DEA sources. First, we obtained copies of docket sheets for all of the registrant actions within the scope of review, which included dates for when charging documents were issued and served, dates of pre-hearing and post-hearing proceedings, and dates the Office of the Administrative Law Judges forwarded registrant actions to the Office of the Administrator.⁵⁹ Second, the Diversion Litigation Section provided data for registrant actions without an ALJ's recommended decision, which included the dates registrant actions were forwarded to the Office of the Administrator for final decision. Finally, we received data from a spreadsheet maintained by the Administrator's Attorney Advisor that included the date the Advisor completed his review of all registrant actions forwarded to the Office of the Administrator, the date a registrant action was forwarded to the Administrator for final decision and signature, and the date the final decision was issued.⁶⁰

⁵⁸ All notices of registrant actions are published in the *Federal Register* and are made available to the public online on the Office of Diversion Control's website at http://www.deadiversion.usdoj.gov/fed_regs/index.html. The notices that we reviewed were under the "Registrant Actions" heading for the years 2008 through 2012.

⁵⁹ The docket sheets the Office of the Administrative Law Judges provided did not include any dates for cases in which the registrant did not request a hearing because those cases were not tracked in the Case Management System. For cases that were tracked in the Case Management System, the docket sheets did not consistently include dates for when a charging document was served on the registrant.

⁶⁰ The Attorney Advisor's spreadsheet included data only since October 2010. Because the spreadsheet did not cover the entire scope of our review, we were not able to use it to identify all of the information we required for our analysis.

APPENDIX II: THE DEA'S RESPONSE TO THE DRAFT REPORT



U. S. Department of Justice
Drug Enforcement Administration

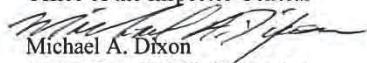
www.dea.gov

Washington, D.C. 20537

APR 25 2014

MEMORANDUM

TO: Nina S. Pelletier
Assistant Inspector General
Evaluation and Inspections
Office of the Inspector General

FROM: 
Michael A. Dixon
Acting Deputy Chief Inspector
Office of Inspections

SUBJECT: DEA's Response to the OIG's Draft Report: *The Drug Enforcement Administration's Adjudication of Registrant Actions*

The Drug Enforcement Administration (DEA) has reviewed the Department of Justice (DOJ), Office of the Inspector General's (OIG) Draft Audit Report, entitled: *The Drug Enforcement Administration's Adjudication of Registrant Actions*. DEA appreciates the efforts of the OIG Audit team to identify areas in which the Agency can improve the efficiency of the manner in which it adjudicates proceedings brought under sections 303 and 304 of the Controlled Substances Act.

The OIG report documents that the adjudicative process followed by the DEA was in compliance with the requirements of 21 U.S.C. §824 and DEA's regulations. Additionally, the OIG noted that there are no federal law or DEA regulations that establish timeliness standards. OIG also noted that DEA has developed more complicated cases against larger distributors which are more likely to result in multiple actions that are then consolidated into a single case, which can result in delays in issuing final decisions.

DEA, however, respectfully disagrees with the OIG Audit Team's finding "that the time it took the DEA to reach a final adjudication of registrant actions was very lengthy" and believes that the Audit Team's methodology gives little or no weight to important factors which impact the timeliness of the adjudicatory process.

Clarifications on Report Findings

I. The OIG's Finding That The Time It Takes DEA To Reach A Final Adjudication Was "Very Lengthy"

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The OIG report found that the average number of days for all registrant actions is 366 days. The OIG report concludes that this timeframe is “very lengthy.” The report does not compare DEA’s timeframes with other components or federal agencies, which conduct adversarial proceedings (or courts) to determine how the timeliness of DEA’s process compares. A true comparison would be necessary to determine if DEA’s timelines are indeed “very lengthy.”

The OIG Report also notes that the Agency has “consistently failed to meet its own timeliness standards in adjudicating immediate suspension orders.” The OIG Report further finds that the Agency has engaged in “excessive delay.” The Report, however, omits material information regarding some of the causes that contribute to delay. More specifically, the Report does not consider that: 1) the state of the record compiled by the ALJ may be such as to greatly increase the time required for reviewing the matter; and 2) a recommended decision may contain both factual and legal inaccuracies which must be addressed and amended by the Agency in its final decision.

II. The OIG’s Findings Regarding Immediate Suspensions Cases Where Registrants Also Lost Their State Authority

The OIG Report notes that “[b]etween 2008 and 2012, the Administrator made a final decision in 13 cases with immediate suspension orders that involved an ALJ’s summary disposition in favor of revocation.” The OIG Report further states “the Office of the Administrator took an average of 203 days to issue a final decision after receiving the case from the Office of Administrative Law Judges.” The OIG Report fails to note that because these individuals did not possess state authority, they could not prescribe controlled substances regardless of whether the federal registration had been revoked. Moreover, while the Agency exceeded its goal for issuing a final decision in these matters, because these individuals did not meet a statutory prerequisite for obtaining a new registration under Federal law, the delay had no impact on them.

III. The OIG’s Finding That Adjudications Have Become Less Timely In Those Matters Which Did Not Involve An ALJ’s Recommended Decision

The OIG Report notes that between 2008 to 2012, the time it took the Office of the Administrator to issue a final decision increased from an average of 98 to 167 days. The Report fails to acknowledge the reason for the increase, *i.e.*, the large number of contested Immediate Suspension proceedings (16) which were brought in the 2011 – 2012 time period. Because these proceedings involved contested Immediate Suspensions, they were given priority review over non-contested matters, with the result that non-contested matters took longer to review.

IV. The OIG Report’s Discussion of How Delays In the Adjudication Process Can Adversely Affect the Public and Registrants

The OIG Report is correct in asserting that delays in the issuance of a final agency decision can potentially affect public health and safety in that a doctor who is issued an Order to Show Cause, but not an Immediate Suspension Order, can continue to divert controlled substances until a revocation order becomes final. However, in the event that

a doctor (or pharmacy) continues to divert drugs during the pendency of a proceeding, the Administrator can, and has, issued an Immediate Suspension Order.

The OIG Report further suggests that delays in resolving immediate suspension cases impose unfair hardships on registrants. However, the OIG Report fails to inform the reader that a registrant can seek injunctive relief from a federal district court in the event the Agency's issuance of an Immediate Suspension Order violates either the Due Process Clause or the requirements of 21 U.S.C. § 824(d).

The OIG Report also does not identify a single case in which a physician or pharmacy subject to an Immediate Suspension Order successfully refuted the allegations raised by the Government, let alone prevailed on judicial review of the Agency's final decision. Indeed, those registrants who have been subject to an Immediate Suspension Order are invariably egregious violators of the Controlled Substances Act.

DEA Response to the Recommendations

The OIG makes three recommendations for DEA action:

Recommendation 1: Establish timeliness guidelines for adjudicating all orders to show cause.

DEA concurs with this recommendation as follows. DEA will promulgate timeliness guidelines for adjudicating orders to show cause consistent with the APA's requirement that agencies conclude matters presented to them "within a reasonable time." 5 U.S.C. § 555(b). Consistent with the APA and in recognition of (i) the highly variable nature of the complexity of the cases DEA initiates; and (ii) the constantly changing nature of diversion itself, DEA anticipates that its guidelines will account for the myriad of factors potentially relevant to an assessment of whether the timeliness of a given adjudication is reasonable.

Recommendation 2: Establish policy and procedures, including timeliness guidelines for forwarding a case to the Office of the Administrator for final decision when a hearing is waived or terminated.

DEA concurs with this recommendation as follows. A DEA working group has been convened to revise DEA's hearing regulations. Although the precise scope and nature of the revisions remains a work in progress, each of the component parts involved in drafting the regulations agrees that DEA should implement a default rule. Such a rule, if implemented, would significantly truncate the work that DEA investigative personnel, CCD attorneys, and the Office of the Administrator must currently perform in connection with requests for Final Agency Action. In the overwhelming majority of Final Agency Actions, the registrant has failed to avail himself/herself of the administrative proceedings that DEA has established to ensure due process. In such instances, DEA regulations currently require DEA to present evidence sufficient to sustain DEA's burden, and the Office of the Administrator must evaluate such evidence and render a

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written decision. As the OIG report correctly recognizes, the nature and extent of the work that is required varies, but can be significant.

The contemplated default rule would eliminate the vast majority of the work that DEA must perform in proceedings where registrants have elected not to proceed, as the allegations in the OTSC/ISO would be deemed admitted. Accordingly, the revised hearing regulations in general, and the default rule in particular, will likely reduce the time it takes DEA to resolve uncontested proceedings, and, in the process, effectively accomplish the purpose underlying this recommendation.

Recommendation 3: Institute a formal process for tracking the timeliness of each adjudication from the initial registration action to the DEA's final decision and for periodically assessing timeliness.

DEA concurs with this recommendation as follows. Since November 2010, the Administrator (and later, the Deputy Administrator) has consistently received quarterly reports with current statistics tracking the timeliness and progress of cases from LJ, and discussed those numbers in significant detail. The process for the review of timeliness of ALJ cases is already in existence, and DEA leadership has been actively engaged in reviewing the numbers and assessing trends. Implementation of the Docket Master System (DMS) enables DEA leadership to have numbers and trends in real-time reports. Screen shots of the completed DMS were previously provided to OIG.

Based on this information, DEA requests closure of this recommendation.

Documentation detailing DEA's efforts to implement concurred recommendations noted in this report will be provided to the OIG on a quarterly basis, until the corrective actions have been completed. If you have any questions or concerns regarding DEA's response to the OIG Audit Report recommendations, please contact the Audit Liaison Team at (202) 307-8200.

APPENDIX III: OIG ANALYSIS OF THE DEA'S RESPONSE

The Office of the Inspector General provided a draft of this report to the Drug Enforcement Administration for its comment. The DEA provided general comments on the report findings and its response to the report's recommendations. The DEA's response is included in Appendix II of this report. The OIG's analysis of the DEA's response and the actions necessary to close the remaining recommendations are discussed below.

GENERAL COMMENTS ON REPORT FINDINGS

I. The OIG's Finding That the Time It Took the DEA to Reach a Final Adjudication Was "Very Lengthy"

DEA Comment: The DEA stated that the OIG report does not compare the DEA's timeframes with other components or federal agencies that conduct adversarial proceedings (or courts) to determine how the timeliness of the DEA's process compares and that a true comparison would be necessary to determine if the DEA's timelines are "very lengthy." The DEA also stated that the OIG report omits material information regarding some of the causes that contribute to delay, including: (1) the state of the record compiled by the ALJ, which may be such as to greatly increase the time required for reviewing the matter; and (2) a recommended decision may contain both factual and legal inaccuracies that must be addressed and amended by the DEA in its final decision.

OIG Analysis: Based on our analysis of the DEA's data compared with parameters established in the DEA's 2006 memorandum, we believe the characterization of the time it takes to reach a final decision as "very lengthy" is accurate. As explained on pages 37 and 38, our analysis of the timeliness of the adjudication process was based on the parameters established in the DEA's 2006 memorandum on the hearing process for immediate suspension orders, which establishes a goal of issuing final decisions within 180 days of a suspension. Because the DEA has not established timeliness standards for orders to show cause, we used the same parameters for both types of orders to ensure our analysis was both consistent and comparable. Based on our analysis of DEA data, we found the average time to adjudicate immediate suspension orders ranged from 647 days in 2008 to 459 days in 2012, substantially above the 180-day goal set in a 2006 DEA memorandum. We also found that it took the DEA on average 616 days in 2008 to 371 days in 2012 to issue a final decision for orders to show cause.

Also, the OIG disagrees with the DEA's statement that the report omits material information regarding some of the causes that contribute to delays in the timeliness of the adjudication process. For example, on page 25, we explain that when cases are received in the Office of the Administrator they are reviewed first by an Attorney Advisor who reads the entire file and drafts a proposed final decision either agreeing with the ALJ's recommended decision or modifying it. We also state that a number of factors, such as the physical length of a case file, can affect how long it takes the Office of the Administrator to review a registrant action and issue a final decision. In addition, pages 20 through 29 explain that enforcement operations and administrative procedures can also affect the timeliness of issuing final decisions.

II. The OIG's Finding Regarding Immediate Suspension Cases Where Registrants Also Lost Their State Authority

DEA Comment: The DEA stated that the OIG report notes that “[b]etween 2008 and 2012, the Administrator made a final decision in 13 cases with immediate suspension orders that involved an ALJ's summary disposition in favor of revocation,” and “the Office of the Administrator took an average of 203 days to issue a final decision after receiving the case from the Office of Administrative Law Judges.” The DEA further stated that the OIG report fails to note that because these individuals did not possess state authority, they could not prescribe controlled substances regardless of whether the federal registration had been revoked. The DEA therefore maintains that, while the DEA exceeded its goal for issuing a final decision in these matters, because these individuals did not meet a statutory prerequisite for obtaining a new registration under federal law, the delay had no impact on them.

OIG Analysis: The OIG highlighted these 13 cases because DEA officials and staff told us that when a registrant lacks state authority DEA precedent compels revocation as the only possible result of the DEA's adjudication. Even if there is no additional impact on the registrants because of restrictions imposed at the state level, we found the time taken for the DEA's adjudication of these cases was excessive because the cases do not require the DEA to perform an extensive legal review before issuing a final decision.

III. The OIG's Finding That Adjudications Have Become Less Timely in Those Matters That Did Not Involve an ALJ's Recommended Decision

DEA Comment: The DEA stated that the OIG report notes that between 2008 to 2012, the time it took the Office of the Administrator

to issue a final decision increased from an average of 98 to 167 days, but the report fails to acknowledge the reason for the increase, i.e., the large number of contested immediate suspension proceedings which were brought in the 2011 to 2012 time period. The DEA stated that because these proceedings involved contested immediate suspensions, they were given priority review over non-contested matters, with the result that non-contested matters took longer to review.

OIG Analysis: The OIG disagrees with the DEA's statement that the report fails to acknowledge the large number of contested immediate suspension proceedings brought in 2011 and 2012. On page 21, the report states that the number of immediate suspension orders that were initiated increased 71 percent throughout our scope, from 24 in 2008 to 41 in 2012, with a high of 65 in 2011. Furthermore, on page 22, the report explicitly states that immediate suspension orders are expedited over other cases.

IV. The OIG Report's Discussion of How Delays in the Adjudication Process Can Adversely Affect the Public and Registrants

DEA Comment: The DEA stated that the OIG report fails to inform the reader that a registrant can seek injunctive relief from a federal district court if the registrant believes the DEA's issuance of an immediate suspension order violates either the Due Process Clause or the requirements of 21 U.S.C. § 824(d). The DEA further stated that the OIG report does not identify a single case in which a physician or pharmacy subject to an immediate suspension order successfully refuted the allegations raised by the government, let alone prevailed on judicial review of the DEA's final decision. The DEA also stated that those registrants who have been subject to an immediate suspension order are invariably egregious violators of the Controlled Substances Act.

OIG Analysis: As explained on pages 37 and 38, the OIG evaluated the DEA's process to adjudicate registrant actions from issuance of a registrant action through a final agency decision. The matters identified in the DEA's response – including the substantive basis for the DEA's issuance of an immediate suspension order, the substantive basis for final agency decisions, and judicial review of such decisions – were beyond the scope of this review, and the OIG consequently cannot express any opinion about them.

OIG'S ANALYSIS OF THE DEA'S RESPONSE TO RECOMMENDATIONS

Recommendation 1: Establish timeliness guidelines for adjudicating all orders to show cause.

Status: Resolved.

Summary of DEA Response: The DEA concurred with this recommendation and stated that for orders to show cause it will promulgate adjudication timeliness guidelines that are consistent with the Administrative Procedures Act and that recognize factors relevant to an assessment of timeliness.

OIG Analysis: The action the DEA plans is responsive to our recommendation. Please provide documentation of the promulgation of timeliness guidelines for adjudicating orders to show cause, or the status of your progress, by August 29, 2014.

Recommendation 2: Establish policy and procedures, including timeliness guidelines for forwarding a case to the Office of the Administrator for final decision when a hearing is waived or terminated.

Status: Resolved.

Summary of DEA Response: The DEA concurred with this recommendation and stated that a working group has been convened to revise the DEA's hearing regulations. The DEA stated that the working group agrees that the DEA should implement a default rule that, if implemented, would significantly truncate the work that DEA personnel must currently perform in connection with requests for a final agency action. The DEA stated that in the majority of registrant actions adjudicated solely by the Administrator, the registrant fails to avail themselves of the administrative proceedings. In such circumstances, DEA regulations currently require the DEA to present evidence sufficient to sustain the DEA's burden and the Office of the Administrator to evaluate such evidence and render a written decision. The DEA stated that the contemplated default rule would eliminate the vast majority of the work that the DEA must perform in proceedings where registrants have elected not to proceed, as the allegations in the registrant action would be deemed admitted. Accordingly, the DEA stated that the revised hearing regulations in general, and the default rule in particular, will likely reduce the time it takes the DEA to resolve uncontested proceedings.

OIG Analysis: The actions the DEA plans are partially responsive to our recommendation.

While instituting a procedural default rule as described in the DEA's response may improve the speed with which these cases are forwarded to the Office of the Administrator, such a rule would not necessarily ensure that DEA staff has been provided with a clear timeliness expectation for forwarding these cases and measured against that standard. We are also concerned that the default rule, as described, may take a significant amount of time to implement, and we therefore encourage the DEA to consider issuing timeliness guidelines prior to the implementation of the default rule. If the default rule, when implemented, improves the efficiency with which these cases are forwarded to the Office of the Administrator, the DEA could adjust its timeliness guidelines as appropriate.

Additionally, we note that under 21 U.S.C. § 877, findings of fact by the Attorney General, or, in this case, the DEA Administrator, are conclusive for purposes of a registrant's appeal of a final determination, but only if supported by "substantial evidence." Before implementing the default rule described in its response, the DEA should evaluate whether a determination based on deemed admissions would satisfy this "substantial evidence" requirement on appeal.

Please provide a copy of the draft hearing regulations, default rule, and other guidance relating to this recommendation, or the status of your progress, by August 29, 2014.

Recommendation 3: Institute a formal process for tracking the timeliness of each adjudication from the initial registration action to the DEA's final decision and for periodically assessing timeliness.

Status: Closed.

Summary of DEA Response: The DEA concurred with this recommendation and provided the OIG with screen shots of the recently implemented Docket Master System to confirm that the DEA has implemented a formal process for tracking the timeliness of each adjudication from the initial registration action to the DEA's final decision, and for periodically assessing timeliness.

OIG Analysis: Based on the actions the DEA has already taken and the OIG's subsequent confirmation of those actions, this recommendation has been closed.